

Remarks

The present invention is directed to liquid-loaded solid carrier particles (substrates) and to a process for loading a solid carrier with a liquid.

Claims 1, 3-14, and 16-20 remain in this application. Claims 2 and 15 are cancelled in this amendment. Claims 1 and 14 are amended to state that the solid carrier particle is selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. Support for these amendments can be found in cancelled claims 2 and 15, respectively.

Rejection Under 35 §USC 103

1. Claims 1, 3-6 and 18 were rejected under 35 §USC 103 (a) as being unpatentable over Handjani et al. (US 6,203,802) in light of Fujiura et al. (US 5,002,986).

In Handjani et al., nanoparticles are the substrates and they are loaded with an active ingredient at from 0.1% to 20% of the total weight of the composition. The substrate nanoparticles are described in col. 3 lines 8-17:

The polymers constituting the biodegradable nanoparticles can be polymers of C₂-C₁₂, and especially C₂-C₆, alkyl cyanoacrylate; the alkyl radical is preferably selected from the group composed of ethyl, n-butyl, hexyl, isobutyl and isohexyl radicals. The biodegradable polymers may also be taken from the group composed of poly-L-lactides, poly-DL-lactides, polyglycolides, polycaprolactones, polymers of 3-hydroxybutyric acid and the corresponding copolymers, such as copoly(DL-lactides/glycolides), copoly(glycolides/caprolactones) and the like.

In the present invention, the solid carrier particle substrate is selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. None of these solid carrier particle substrates of claim 1, as amended, are described as biodegradable nanoparticle substrates in Handjani et al.

Fujiura et al. teach a fluid absorbent polymer substrate composition having a high rate of absorbency. As stated in the abstract, the utility of this absorbent polymer composition is in diapers, sanitary napkins and incontinent devices. The fluid absorbent polymer substrate is prepared by contacting an absorbent base polymer with an aqueous solution of a crosslinker under high intensity mixing conditions to surface crosslink the

absorbent base polymer substrate particles and to agglomerate them into larger-sized particles.

The absorbent base polymers are described in col. 5 lines 35-46:

The absorbent base polymers useful in the invention are known. They may be selected from a crosslinked, partially neutralized polyacrylic acid (see U.S. Pat. No. 4,654,039), a crosslinked, partially neutralized starch-acrylic acid graft polymer (U.S. Pat. No. 4,076,663), a crosslinked, partially neutralized copolymer of isobutylene and maleic anhydride (U.S. Pat. No. 4,389,513), a saponification product of vinyl acetate-acrylic acid copolymer (U.S. Pat. No. 4,124,748), a hydrolyzate of acrylamide polymer or acrylamide copolymer (U.S. Pat. No. 3,959,569) or a hydrolyzate of an acrylonitrile copolymer (U.S. Pat. No. 3,935,099). The teachings of the above patents are hereby incorporated by reference. All of the above described fluid absorbent base polymers can be used to make absorbent compositions within this invention as well as any fluid absorbent polymer provided the base polymer has a free absorbency of at least 3 ml/gm.

The aqueous crosslinkers are described in col. 6 lines 42-46:

Effective surface crosslinkers are polyvalent metal salts, oxides, hydroxides and other compounds which are soluble in water and which dissociate in water. In addition, organic amines and polyimines have been found to be effective ionic crosslinkers. Although heating is generally not necessary, the base polymer may be optionally heated during the crosslinking and agglomeration process.

In the present invention, the solid carrier particle substrate is selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. None of these solid carrier particle substrates of claim 1, as amended, are described as absorbent base polymers in Fujiura et al.

Combining Handjani et al. with Fujiura et al. as urged in the Office Action does not render the present invention as obvious. Both Handjani et al. and Fujiura et al. use organic polymers in making their substrates. The present invention does not use the organic polymers of Handjani et al. and Fujiura et al. in its substrate.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary

skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the teachings of Handjani et al. in light of Fujiura et al. fail to teach or suggest all of the claim limitations of Applicants' claims 1, 3-6 and 18, and further that there is no motivation by one of ordinary skill in the art for employing limitations present in claims 1, 3-6 and 18, not present in Handjani et al. and Fujiura et al. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

2. Claim 8 was rejected under 35 §USC 103 (a) as being unpatentable over Handjani et al. and Fujiura et al. in light of Barnhart et al. (US 5,762,952). Claim 8 depends from amended claim 1.

Both Handjani et al. and Fujiura et al. are discussed above.

Barnhart et al. teach an article of manufacture which is useful for the efficacious delivery of an active drug transdermally. In Barnhart et al., a transdermal drug (nitroglycerin) is incorporated into a self-crosslinking acrylic multipolymer adhesive substrate coated onto a flexible barrier film and protected by an impervious release liner. The Barnhart et al. multipolymers are esters of acrylic acid that undergo crosslinking with any group offering an available active hydrogen, such as amido, amino, carboxyl, hydroxyl and thio groups.

In the present invention, the solid carrier particle substrate is selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. None of these solid carrier particle substrates of claim 1, as amended, are described as absorbent base polymers in Barnhart et al.

Combining Handjani et al. and Fujiura et al. with Barnhart et al., as urged in the Office Action does not render present claim 8 as obvious. Claim 8 depends from amended claim 1. Handjani et al., Fujiura et al. and Barnhart et al. all use organic polymers in making their substrates. The present invention does not use the organic polymers of Handjani et al., Fujiura et al. and Barnhart et al in its substrate.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation,

either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the teachings of Handjani et al. and Fujiura et al. in light of Barnhart all fail to teach or suggest all of the claim limitations of Applicants' claim 8 that depends from amended claim 1, and further that there is no motivation by one of ordinary skill in the art for employing limitations present in claim 8 that depends from amended claim 1, not present in Handjani et al., Fujiura et al., and Barnhart et al. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

3. Claims 1, 5-6, 14, and 18 were rejected under 35 §USC 103 (a) as being unpatentable over Zaffaroni (US 3,921,636) in light of Fujiura et al. (US 5,002,986).

Fujiura et al. is discussed above.

Zaffaroni is directed to a drug delivery device for administering drugs at a controlled rate for a prolonged period of time. The device comprises a plurality of substrate reservoirs containing drugs distributed through a matrix. The materials suitable for fabricating the substrate reservoirs are stated in col. 7 lines 8-31:

Exemplary materials suitable for fabricating the rate controlling microcapsules include poly(methylmethacrylate), poly(butylmethacrylate), plasticized or unplasticized poly(vinylchloride), plasticized nylon, plasticized soft nylon, plasticized poly(ethylene terephthalate), natural rubber, poly(isoprene), poly(isobutylene), poly(butadiene), poly(ethylene), poly(tetrafluoroethylene), poly(vinylidene chloride), poly(acrylonitrile), poly(vinylpyrrolidone), poly(vinyl methyl ether), poly(trifluorochloroethylene), poly (4,4'-isopropylidene diphenylene carbonate), sodium (polystyrene sulfonate), copolymers such as ethylene-vinylacetate, vinylidene chloride acrylonitrile, vinyl chloride diethyl fumarate, and the like. Examples of other materials include silicone rubbers, especially the medical grade poly(dimethylsiloxanes), and silicone-carbonate copolymers; hydrophilic polymers such as the hydrophilic hydrogels of esters of acrylic and methacrylic acid (as described in U.S. Pat. Nos. 2,976,576 and 3,220,960 and Belgian Pat. No. 701,813, modified collagen, cross-linked polyvinylalcohol, cross-linked partially hydrolyzed polyvinylacetate. Other polymeric membranes that are biologically compatible and do not adversely affect the drugs can be used.

In the present invention, the solid carrier particle substrate is selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. None of these solid carrier particle substrates of claim 1, as amended, are described as biodegradable nanoparticles in Zaffaroni.

Combining Zaffaroni and Fujiura et al. as urged in the Office Action does not render present claims 1, 5-6, 14, and 18 as obvious. Zaffaroni and Fujiura et al. use organic polymers in making their substrates. The present invention does not use the organic polymers of Zaffaroni and Fujiura et al.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the teachings of Zaffaroni in light of Fijura et al. fail to teach or suggest all of the claim limitations of Applicants' claims 1, 5-6, 14, and 18, and further that there is no motivation by one of ordinary skill in the art for employing limitations present in claims 1, 5-6, 14, and 18 not present in Zaffaroni and Fujiura et al. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

4. Claim 8 was rejected under 35 §USC 103 (a) as being unpatentable over Zaffaroni and Fujiura et al. in light of Barnhart et al. Claim 8 depends from amended claim 1.

These three references are all discussed above.

In the present invention, the solid carrier particle substrate is selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. None of these solid carrier particle substrates of claim 1, as amended, are described as biodegradable nanoparticle substrates in Zaffaroni, Fujiura et al., and Barnhart et al.

Combining Zaffaroni, Fujiura et al. and Barnhart et al. as urged in the Office Action does not render present claim 8 which depends from claim 1 as obvious. Zaffaroni, Fujiura et al. and Barnhart et al. all use organic polymers in making their

substrates. The present invention does not use the organic polymers of Zaffaroni, Fujiura et al. and Barnhart et al.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the teachings Zaffaroni, Fujiura et al. and Barnhart et al. fail to teach or suggest all of the claim limitations of Applicants' claim 8, which depends from claim 1 and further that there is no motivation by one of ordinary skill in the art for employing limitations present in claim 8 which depends from amended claim 1 not present in Zaffaroni, Fujiura et al. and Barnhart et al. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

5. Claim 6 was rejected under 35 §USC 103 (a) as being unpatentable over Zaffaroni and Fujiura et al. in light of Rubin (US 4,961,936). Claim 6 depends from amended claim 1.

Zaffaroni and Fujiura et al. are discussed above.

Rubin is cited for its teachings of polyunsaturated fatty acids, such as EPA and DHA. However, both Zaffaroni and Fujiura et al. both employ polymeric materials as substrates and not the present claim 1, as amended, solid carrier particle substrate selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. None of these solid carrier particle substrates of claim 1, as amended, are described as biodegradable nanoparticle substrates in Zaffaroni and Fujiura et al.

Combining Zaffaroni, Fujiura et al. and Rubin as urged in the Office Action does not render present claim 6 which depends from claim 1 as obvious. One would not read the teachings of Zaffaroni and Fujiura et al. directed to the use of organic polymers in making their substrates to arrive at the present invention which does not use organic polymers.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the teachings Zaffaroni, Fujiura et al. and Rubin fail to teach or suggest all of the claim limitations of Applicants' claim 6 which depends from amended claim 1, and further that there is no motivation by one of ordinary skill in the art for employing limitations present in claim 6 which depends from amended claim 1 not present in Zaffaroni, Fujiura et al. and Rubin. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

6. Claims 2, 7, 9-13, 15-16 and 19-20 were rejected under 35 §USC 103 (a) as being unpatentable over Zaffaroni and Fujiura et al. in light of Lech et al.

Zaffaroni and Fujiura et al. are discussed above.

Lech et al. teach a chewable tablet medication comprising two active cold medications onto a silicon dioxide absorbent substrate material, which masks the bitter metallic taste and numbing mouth feel of the cold medications. The tablet is formed by dissolving the active cold medications in water. A clear solution is achieved which is combined with silicon dioxide and thoroughly blended. The mixture is then dried in a forced hot air oven.

It is noted in Lech et al. that the water is removed. Consequently, a product is obtained that has zero percent liquid. In present claim 1, from which claims 2, 7, and 9-13 depend, and present claim 14, from which claim 16 depends, the solid carrier particle substrate is loaded with at least 60% liquid. In Lech et al., since its product is dried, the liquid content is close to zero percent. In present independent claims 1 and 14, the solid carrier particle substrate has a size of less than 100 nm. Lech et al. do not teach any particle size on the silicon dioxide substrate. Present claims 1 and 14 are amended to

define the solid carrier particle substrates of silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments.

Combining Zaffaroni and Fujiura et al. with Lech et al., as urged in the Office Action does not render Applicants' claims 2, 7, 9-13, 15-16 and 19-20, which depend from amended claims 1 and 14 as obvious. Zaffaroni and Fujiura et al. use organic polymers in making their substrates. While Lech et al. teach silicon dioxide as a substrate, Lech et al. do not teach the present particle size of under 100 nm. Lech et al. teach away from the present liquid content of at least 60%, as Lech et al. teach a liquid content of close to zero percent.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the teachings Zaffaroni, Fujiura et al. and Lech et al. fail to teach or suggest all of the claim limitations of Applicants' claims 2, 7, 9-13, 15-16 and 19-20, which depends from amended claims 1 and 14, and further that there is no motivation by one of ordinary skill in the art for employing limitations present in claims 2, 7, 9-13, 15-16 and 19-20, which depend from amended claims 1 and 14, not present in Zaffaroni, Fujiura et al. and Lech et al. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

7. Claim 17 was rejected under 35 USC 103 (a) as being unpatentable over Zaffaroni, Fujiura et al. and Lech et al. as applied to claim 16 and further in view of Rubin (US 4,961,936).

Claim 17 ultimately depends from amended claim 14.

Combining Zaffaroni, Fujiura et al., and Lech et al., further in view of Rubin, as urged in the Office Action does not render Applicants' claim 17, which ultimately depends from amended claim 14 as obvious. Zaffaroni and Fujiura et al. use organic polymers in making their substrates. Polymeric materials as substrates are not present in

amended claim 14. The present solid carrier particles are selected from silicas, titanium dioxide, zeolites, alumina, carbon nanotubes, activated carbon, carbon black and pigments. While Lech et al. teach silicon dioxide as a substrate, Lech et al. do not teach a particle size of under 100 nm. Lech et al. teach away from the present liquid content of at least 60%, as Lech et al. teach a liquid content of close to zero percent. Rubin is cited for its teachings of polyunsaturated fatty acids, such as EPA and DHA. However combining the teachings of Rubin with Zaffaroni, Fujiura et al., and Lech et al., do not render the present invention as obvious.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the teachings of Zaffaroni, Fujiura et al. and Lech et al. and further in view of Rubin fail to teach or suggest all of the claim limitations of Applicants' independent claim 14 from which claim 17 depends. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

In the event the Examiner finds minor issues within this case remain unresolved, the Examiner is respectfully requested to contact the undersigned to arrange for an interview to expedite the disposition of this application.

If any additional fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-0421.

Respectfully submitted,
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